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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 22

Application Number: 09/002,485
Filing Date: 31 December 1997
Appellant(s): Lal et al.

Richard C. Ekstrom
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 31 August 2001.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is deficient because the claimed invention is directed to isolated polynucleotides encoding SEQ ID NO:25, or having a sequence of SEQ ID NO:102, cells transformed with said polynucleotide, methods for producing the encoded polypeptide, polynucleotides comprising contiguous portions of a polynucleotide having the sequence of SEQ ID NO:102, compositions comprising said polynucleotide and microarrays containing a contiguous portion of a polynucleotide having the

sequence of SEQ ID NO:102. Therefore, Appellant's statement that the invention is directed to uses of these polynucleotides is not correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: (1) whether claims 24-27 and 29-33 possess an asserted specific, substantial and credible utility or well-established utility to satisfy the utility requirement 35 U.S.C. § 101 and (2) whether one of ordinary skill in the art would know how to use the invention as recited in claims 24-27 and 29-33 so as to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph.

(7) Grouping of Claims

The appellants provide a statement in the brief that the claims stand or fall together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

Vicari et al. "TECK: A Novel CC Chemokine Specifically Expressed by Thymic Dendritic Cells and Potentially Involved in T Cell Development." Immunity, vol. 7 (August 1997), pp. 291-301. (Cited by Appellant).

Rossi et al. "The Biology of Chemokines and Their Receptors" Annu. Rev. Immunol. Vol. 18 (2000), pp. 217-242. (Cited by Appellant).

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 24-27 and 29-33 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a well-established or a disclosed specific and substantial credible utility. This rejection is set forth in prior Office Action of 09 June 2000, Paper No. 12.

As stated therein, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of this protein or its significance. The instant specification asserts that it provides compositions that may be used for diagnosis, treatment and prevention of cancer and immunological disorders (see specification at pages 17-18). The instant specification does not indicate that the claimed invention could be used for toxicology testing or drug discovery and fails

to identify any cancers or immunological disorders which could be treated, prevented or diagnosed with the claimed invention.

These utilities are not considered to be specific and substantial because the specification fails to disclose any particular function or biological significance for the signal peptide-containing protein (SEQ ID NO:25) and the polynucleotide encoding it (SEQ ID NO:102) of the instant invention. The disclosed protein, whose cDNA has been isolated and is claimed, is said to have a potential function based upon its amino acid sequence similarity to other known proteins. After further research, a specific and substantial credible utility might be found for the claimed isolated compositions. This further characterization, however, is part of the act of invention and until it has been undertaken, Appellant's claimed invention is incomplete.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to a polynucleotide encoding a protein of as yet undetermined function or biological significance. There is absolutely no evidence of record or any line of reasoning that would support a conclusion that the claimed polynucleotide encoding a signal peptide-containing protein was, as of the filing date, useful "in the diagnosis, treatment and prevention of cancer and immunological disorders" as stated at page 14 of the specification. Until some actual and specific significance can be attributed to the protein of SEQ ID NO:25, encoded by the polynucleotide of SEQ ID NO:102, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Thus, there was no immediately apparent or "real world" utility as of the filing date.

The polynucleotide of the instant invention and the protein encoded thereby are compounds which contain signal peptides. The specification indicates that proteins which contain signal peptides include G-protein coupled receptors, tetraspanins, MPs, lectins, protein kinases, protein phosphatases, protein phosphatase inhibitors, cyclic nucleotides, phospholipases, nucleotide cyclases, chemokines, growth and differentiation factors, proteolytic enzymes, zinc proteases, guanosine triphosphate-binding proteins, ion channels, ion

pumps, membrane proteins, amino acid transporters, proton-coupled transporters, hormones, neuropeptides, and transcription factors (see pages 1-13 of the specification). At page 47 of the specification, the protein of SEQ ID NO:25 is indicated to share 28% sequence identity with mouse beta chemokine, however, this is not a disclosure of how to use the protein (or the polynucleotide encoding it) because chemokines are a broad class of proteins which have divergent biological activity which cannot be predicted based on amino acid sequence information alone. In the absence of a knowledge of what the protein of SEQ ID NO:25 is, what receptor binds this protein, or the biological significance of this protein, there is no immediately obvious patentable use for it or the polynucleotide encoding it. To employ a polynucleotide encoding the protein of SEQ ID NO:25 of the instant invention in any of the disclosed methods would clearly be using it as the object of further research. Such a use has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for claimed polynucleotide encoding the protein of SEQ ID NO:25, then the claimed invention as disclosed does not meet the requirements of 35 U.S.C. §101 as being useful.

Claims 24-27 and 29-33 are also rejected under 35 U.S.C. §112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. §101. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well-

established utility for the reasons set forth above, one skilled in the art wold not know how to use the claimed invention so that it would operate as intended without undue experimentation.

(11) Response to Argument

Appellant asserts that the claimed polynucleotide is expressed in gastrointestinal, developmental, hematopoietic, and immunological tissues (see page 3 of the Brief). Appellant also suggests that the protein encoded by the claimed polynucleotide is 150 amino acids in length and shares 28% sequence identity with mouse beta chemokine (see page 4 of the Brief). Appellant further asserts that "[r]ecent BLAST analysis provides evidence that SEQ ID NO:25 is a chemokine" and that the encoded protein of the claimed polynucleotide has 98% sequence identity to a chemokine specifically expressed by thymic dendritic cells (TECK) and is potentially involved in T-cell development (see page 4 of the Brief) as is evidenced by Vicari et al.

Appellant's arguments have been fully considered, however are not persuasive. The specification as originally filed must provide a specific, substantial and credible utility for the claimed invention or there must be a well-established utility for the claimed invention at the time the application was filed. Based on the disclosure of 28% amino acid sequence identity of the encoded protein to a mouse chemokine does not provide for a specific, substantial and credible utility for the claimed invention. Although one of ordinary skill in the art may reasonably conclude that the claimed polynucleotide encodes a protein which could be

classified as a chemokine based on structure, the members of this class of proteins do not possess a well-established utility as the biological effects of each member of the class depend on their tissue expression and the receptor to which the chemokine binds. The biological significance of the claimed polynucleotide is not disclosed and cannot be ascertained from the information provided in the instant specification. Appellant's statement regarding the high degree of sequence identity to another chemokine expressed by thymic dendritic cells is noted, however, this reference does not provide a specific, substantial and credible utility for the invention as claimed because the specification does not support use of the claimed invention as a thymic dendritic cell-specific CC chemokine, as asserted in Vicari et al. There is no suggestion in the specification as filed that the claimed polynucleotide is expressed in the thymus or may be involved in T-cell development, absent evidence to the contrary.

Appellant's summary of the biological effects of chemokines at page 4 of the Brief is noted. However, as Appellant asserts, chemokines have actions on the immune system, central nervous system, and endothelial cells that are involved in angiogenesis or angiostasis. Such activity is dependent on the chemokine receptor which is expressed in a particular tissue and by the chemokine expressed in the target organ (as evidenced by Rossi et al., cited by Appellant). The instant specification fails to disclose the biological significance or biological role of the claimed invention in order for one of ordinary skill in the art to use it in a specific and substantial manner. The specification does not teach what biological effects are mediated by the claimed invention, what receptor the encoded protein binds to, the target tissue for the

encoded protein, etc. Will the encoded protein stimulate the immune system, inhibit the immune system, what effect would be found on the central nervous system if any, would it be useful in inhibition of tumor cells or should inhibition be required, and if so, which tissues will be responsive to the encoded protein? Appellant's specification fails to provide a specific and substantial credible utility for the claimed invention and the assertion that the claimed polynucleotide encodes a chemokine protein does not remedy this deficiency as there is no well-established utility which can be attributed to the entire class of proteins categorized as chemokines for the reasons provided above. Appellant further asserts at page 5 of the Brief that "[b]ased on the instant specification, and the knowledge available to one of ordinary skill in the art, the practitioner would not doubt that SEQ ID NO:25 is a human lymphocyte-specific chemokine". Appellant's assertion is faulted by the instant specification as lymphocyte specificity is not demonstrated by the array of tissues which express the claimed polynucleotide and the data of Vicari et al. which concludes that a related protein is thymic dendritic cell-specific, not lymphocyte-specific.

Appellant summarizes case law on the utility requirement at pages 5-6 of the Brief. The essential disagreement appears to be the interpretation of what constitutes a specific, substantial and credible utility, as will be explained more fully below.

Appellant argues at pages 6-9 of the Brief that the claimed polynucleotides are useful as tools for toxicology testing, drug discovery, and the diagnosis of disease and that these uses are "well-established". It is noted that toxicology testing and drug discover are not

specifically recited in the specification as originally filed. Each of these uses will be addressed individually, because the facts and issues directed to each use are distinct and separable. First, Appellant argues that toxicology testing is a well-established utility and conclude that the claimed polynucleotides could be used in this manner and that the claimed invention possesses utility. However, for a utility to be "well-established" it must be specific, substantial and credible. In this case, as indicated at page 7 of the Brief, all nucleic acids and genes are in some combination useful in toxicology testing. However, the particulars of toxicology testing with SEQ ID NO:102 are not disclosed in the instant specification. Neither the toxic substances nor the susceptible organ systems are identified. Therefore, this is a utility which would apply to virtually every member of a general class of materials, such as any collection of proteins or DNA, but is only potential with respect to SEQ ID NO:102. Because of this, such a utility is not specific and does not constitute a "well-established" utility. Further, because any potential diagnostic utility is not yet known and has not yet been disclosed, the utility is not substantial because it is not currently available in practical form. Moreover, use of the claimed polynucleotide in an array for toxicology screening is only useful in the sense that the information that is gained from the array is dependent on the pattern derived from the array, and says nothing with regard to each individual member of the array. Again, this is a utility which would apply to virtually ever member of a general class of materials, such as any collection of proteins or DNA. Even if the expression of Appellant's individual polynucleotide is affected by a test compound in an array for drug screening, the specification does not

disclose any specific and substantial interpretation for the result, and none is known in the art. Given this consideration, the individually claimed polynucleotide has no "well-established" use. The artisan is required to perform further experimentation on the claimed material itself in order to determine to what "use" any expression information regarding this nucleic acid could be put.

With regard to drug discovery and development, Appellant mentions expression profiling as one use of the claimed polynucleotide (see page 8 of the Brief). Expression profiling is usually performed by use of transcript imaging which is a method for quantifying the relative expression levels of a large number of gene transcripts within a biological sample. In this manner, a gene expression profile is generated. Such a profile is independent of the function of the genes or gene products. In the instant case, Appellant asserts that the claimed polynucleotides can be used as one of many targets on a microarray for expression profiling. Appellant asserts that the claimed polynucleotides could be used for biochemical pathway elucidation, drug target identification, and assessment of toxicity and treatment efficacy in the drug development process.

However, Appellants are incorrect in asserting that the efficacy (ability of producing a desired effect) of a compound could be evaluated from the result of expression profiling because there is no way to assess the meaning of any individual hit obtained from this procedure. The first requirement is that one must know the biological significance of the polynucleotide(s) which is(are) being evaluated. Without this information, the results of the

expression profiling or transcript image are useless because one would not know if the polynucleotide expression should be increased or decreased or even what significance could be attributed to such changes in expression profiles. The specification alleges that the claimed polynucleotide encodes a protein which is useful for treatment, prevention and diagnosis of immune disorders and cancer. However, there is no evidence of record that the disclosed protein or claimed polynucleotide is associated with any immune disorder or cancer. Without knowledge of what tissue the claimed invention acts on and the biological significance of such action, one of ordinary skill in the art at the time the instant invention was made would not be able to use the information obtained from a transcript image in a useful manner. There is no evidence to the contrary.

With regard to diagnosis of disease, in order for a polynucleotide to be useful, as asserted, for diagnosis of a disease, there must be a well-established or disclosed correlation or relationship between the claimed polynucleotide and a disease or disorder. The presence of a polynucleotide in tissue that is derived from cancer cells is not sufficient for establishing a utility in diagnosis of disease in the absence of some information regarding a correlative or causal relationship between the expression of the claimed cDNA and the disease. If a molecule is to be used as a surrogate for a disease state, some disease state must be identified in some way with the molecule. There must be some expression pattern that would allow the claimed polynucleotide to be used in a diagnostic manner. Many proteins are expressed in normal tissues and diseased tissues. Therefore, one needs to know, e.g., that the claimed

polynucleotide is either present only in cancer tissue to the exclusion of normal tissue or is expressed in higher levels in diseased tissue compared to normal tissue (i.e. overexpression). Evidence of a differential expression might serve as a basis for use of the claimed polynucleotide as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed polynucleotide or the protein that is encoded thereby and any disease or disorder and the lack of any correlation between the claimed polynucleotide or the encoded protein with any known disease or disorder, any information obtained from an expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner*, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

At page 9 of the Brief, Appellant argues that "[t]here is no authority for the proposition that use SEQ ID NO:25 and SEQ ID NO:102 as tools for research is not a substantial utility" and that "[o]nly a limited subset of research uses as not "substantial" utilities: those in which the only known use for the claimed invention is to be an object of further study" (emphasis omitted). However, in the instant situation, the only known use for the claimed invention is as an object for further research, in that the asserted utilities are not found to be specific, substantial and credible for the reasons provided above and below. The asserted uses of toxicology testing, drug discovery, and disease diagnosis (which are not supported by the

instant specification as filed) are not specific, substantial and credible as explained above. In order to obtain useful information for the claimed "tool" (polynucleotide), one of ordinary skill in the art would need to know the biological significance of the claimed polynucleotide, otherwise no meaningful interpretation could be obtained from any data generated by using the claimed polynucleotide in the asserted methods.

At page 10 of the Brief, Appellant argues that "the rejection is made based on a scientifically incorrect and legally unsupportable assertion that the identification of the family or families of proteins to which the claimed invention belongs, without more, does not satisfy the utility requirement". The rejection is based on the failure to disclose sufficient properties of the protein and/or polynucleotide to support an inference of utility. The protein family (i.e. chemokines) to which the polypeptide encoded by the claimed polynucleotide belongs is a family in which the members have divergent functions based on which tissues the protein is expressed or administered to, wherein the function of the protein is dependent on not only the tissue in which it is expressed, but also the receptor to which it binds. Assignment to this family does not support an inference of utility because the members are not known to share a common utility. There are some protein families for which assignment of a new protein in that family would convey a specific, substantial and credible utility to that protein. For example, some families of enzymes such as proteases, ligases, telomerases, etc. share activities due to the particular specific biochemical characteristics of the members of the protein family such as non-specific substrate requirements, that are reasonably imputed to isolated

compositions of any member of the family. Without knowing a biological significance of the claimed polynucleotides or the polypeptide encoded thereby, one of ordinary skill in the art would not know how to use the claimed invention in its currently available form in a credible "real world" manner based on the diversity of biological activities possessed by the chemokine family. Contrast *Brenner*, 148 USPQ at 694 (despite similarity with adjacent homologue, there was insufficient likelihood that the steroid would have similar tumor-inhibiting characteristics), with *In re Folkers*, 145 USPQ 390, 393 (CCPA 1965) (some uses can be immediately inferred from a recital of certain properties) or *In re Brana*, 34 USPQ 1436, 1441 (Fed. Cir. 1995) (evidence of success in structurally similar compounds is relevant in determining whether one skilled in the art would believe an asserted utility; here, an implicit assertion of a tumor target was sufficiently specific to satisfy the threshold utility requirement).

At page 10 of the Brief, Appellant argues that a patent application can specify a utility without any knowledge as to how or why the invention has that utility. Nevertheless, the utility must be specific, substantial and credible. Appellant's assertion that the claimed invention has utility in toxicology testing, drug development and disease diagnosis, as well as in the treatment, prevention and diagnosis of immune disorders and cancer do not meet the standards for a specific, substantial, and credible or well-established utility for reasons set forth above.

At page 11 of the Brief, Appellant states "unlike the synthetic molecules of Kirk, the claimed invention is known to be useful" (emphasis omitted) in toxicology testing, drug

development and disease diagnosis. Appellant states that the "claimed invention could be used, for example, in a toxicology test to determine whether a drug or toxin causes any change in the expression of growth factors". However, the specification does not disclose the significance of any test results, nor is there any evidence that the significance was known as of the filing date. If the expression of the claimed polynucleotide increases, is this a positive or negative outcome? Would this be a toxic response or not? The disclosure is insufficient to evaluate the results of the test in any meaningful manner. Appellant suggests that "the claimed invention could be used, for example, in a toxicology test to determine whether a drug or toxin causes any change in the expression of lymphocyte-specific chemokines". This asserted utility finds no support in the instant specification as filed, and is contrary to the evidence of Vicari et al. which would suggest that the claimed polynucleotide does not encode a "lymphocyte-specific chemokine".

Appellant further argues that the claimed polynucleotide could serve "as a marker of a toxic response, or alternatively, if levels of the claimed polynucleotide remain unchanged during a toxic response, as a control in toxicology testing" (page 11 of the Brief, final paragraph). However, this use is speculative at best, as well as not being specific or substantial in that any polynucleotide may possess the property of being a marker for some toxic response. It would appear that Appellant is describing a "wish to know" type of utility, which is not a specific, substantial and credible utility. Appellant asserts that knowledge of the specific functions of the encoded protein, i.e. the function or role of the protein in its natural

state, is not required for use of the polynucleotide in diagnosis of disease. The validity of this argument requires some correlation to a disease. On this record, such a correlation is absent.

At page 12 of the Brief, Appellant argues that a utility may be specified even if it applies to a broad class of inventions. The proposition is not sufficient to establish utility for each member of the class. Specific utility must be shown or be evident for each member of the class. None of the utilities identified by Appellant, i.e. toxicology testing, drug discovery, disease diagnosis, connective tissue modulator, have been demonstrated to be specific to SEQ ID NO:25 or 102. One of ordinary skill in the art must understand how to achieve an immediate and practical benefit from the claimed species based on the knowledge of the class. However, no practical benefit has been shown for the use of SEQ ID NO:25 or 102.

Appellant argues at pages 12-14 of the Brief that practical utility of an invention may be derived from belonging to a broad class of inventions. The requirement in any particular case, however, is that practical utility can be inferred if each and every member of the broad class possesses a common utility. However, the fact situation in the instant application is not analogous to Appellant's fishing pole example. Appellant's expansion of this concept to different "classes" of proteins with the assertion that each "class" possesses a specific, substantial and credible or well-established utility is not persuasive. Whether the cited classes of proteins (interleukins, G-protein coupled receptors, DNA ligases) do or do not possess a specific, substantial and credible or well-established utility is not to be decided in the instant application because the instant claims are not directed to interleukins, G-protein coupled

receptors or DNA ligases. Rather, the question in the instant application is whether the members of the family of proteins to which the claimed invention is structurally related have, individually, a specific, substantial and credible or well-established utility.

Appellant argues that "all of the lymphocyte-specific chemokines are expressed by humans, and all of them can be used as tools for toxicology testing" (see page 14 of the Brief). This argument is not persuasive because, first, the instant specification and the prior art fail to establish that the claimed polynucleotide encodes a "lymphocyte-specific". In fact, Vicari et al. teach that a protein which is structurally similar to the encoded protein of the claimed polynucleotide is inactive on peripheral blood lymphocytes (see column 2, paragraph 3). Secondly, use of the claimed invention for use in toxicology testing has already been addressed and not found to be a specific, substantial and credible utility. Moreover, the evidence of record is inadequate to determine the disease(s), drug(s) or toxicological screen(s) for which the claimed compounds would be useful. In *Brenner,* the Court approved a rejection for failure to disclose any utility for a compound where the compound was undergoing screening for possible tumor-inhibiting effects and an adjacent homologue of the compound had proven effective. *Brenner*, 148 USPQ at 690. Here, there is no evidence that the claimed isolated compounds have any specific, substantial and credible utility. Appellant further asserts that the "claimed invention has numerous other uses, including: stimulating lymphocytes to boost immune response, attracting or repelling lymphocytes to/from sites of infection, inflammation, or tissue damage, and repelling lymphocytes from tissues of the central nervous system

following trauma". It should be noted that the instant specification fails to assert these uses as iterated in the Brief at page 14, and further, there is no evidence to support use of the claimed polynucleotides for these purposes as the biological activity of the encoded protein is not disclosed. Lastly, Appellant's assertion encompasses divergent activities, therefore, without knowing whether the claimed polynucleotide could be used for "attracting or repelling", one of ordinary skill in the art would be unable to use the claimed invention in a reasonable manner. In order to use the invention in a meaningful manner, one of ordinary skill in the art would need to know which of the multitude of biological activities which may be possessed by various members of the protein family to which the claimed invention is alleged to belong, are possessed by the newly identified member. The assertion that the claimed invention is related to chemokines and immune response without information on the specific type of tissue affected and the characteristics of the effect represents no more than an invitation to experiment to find a use for the claimed compound. Such an invitation is not a disclosure of how to use the invention in a real-world context that 35 U.S.C. § 101 requires.

For all the above reasons, the disclosure is insufficient to teach one of skill in the art how to use the invention. A review of *In re Wands,* 8 USPQ2d 1400 (CAFC 1988) clearly points out the factors to be considered in determining whether a disclosure would require undue experimentation and include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in

the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. All of these factors are considerations when determining the whether undue experimentation would be required to use the claimed invention. As is evidence in the discussions *supra*, each of these factors has been carefully considered in the instant grounds of rejection, and it is maintained that undue experimentation would be required by the skilled artisan to use the instant invention.

Appellant asserts at page 14 of the Brief that the use of the claimed invention for toxicology testing, drug discovery, and disease diagnosis are real-world utilities. The question at issue is whether or not the broad general assertion that the claimed nucleic acids might be used for *some* diagnostic application in the absence of a disclosure of *which* diagnostic application would be considered to be an assertion of a specific, substantial, and credible utility. For reasons set forth above the disclosure satisfies none of the three criteria *See In re Kirk*, 153 USPQ 48, 53 (CCPA 1967) (quoting the Board of Patent Appeals, 'We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.')

Appellant asserts at page 15 of the Brief that there exists a market "for databases containing all expressed genes". However, this assertion fails to address the utility of the individually claimed polynucleotide of the invention of the instant application. The claims are to isolated chemical compositions, not to descriptive information included in a database.

Appellant argues at page 15 of the Brief that the Examiner failed to demonstrate that one of ordinary skill in the art would reasonably doubt the utility of the claimed invention. This argument is not persuasive because such evidence and scientific reasoning was presented in the grounds of rejection in paper #12 and reiterated in the grounds of rejection above. Appellant asserts at page 16 of the Brief that the claimed invention is "in fact a lymphocyte-specific chemokine, which is known to have a specific utility". However, for reasons set forth above, Appellant has not presented sufficient evidence to support specific utility for SEQ ID NO:25 or 102. The present rejection under § 101 follows *Brenner v. Manson*, as set forth above. In that case, the absence of a demonstrated specific utility for the claimed steroid compound was not ameliorated by the existence of a demonstrated general utility for the class. Unlike *Fujikawa v. Wattanasin*, where there were pharmaceutically acceptable *in vitro* results, here, there is nothing other than relatively low levels of sequence homology to a broad and diverse family of proteins having distinct modes of activity, and no disclosed common mode of action. As Appellant recognizes, a rejection under § 112, first paragraph, may be affirmed on the same basis as a lack of utility rejection under § 101. *See, e.g., In re Swartz*, 56 USPQ2d 1703 (Fed. Cir. 2000); *In re Kirk*, 153 USPQ 48 (CCPA 1967).

Therefore, for reasons set forth above, Appellant's arguments and exhibits have been fully and carefully considered, but are not considered sufficient to rebut the *prima facie* case of lack of utility and it is believed that the rejections should be sustained.

Respectfully submitted,

Christine J. Saoud
November 16, 2001

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